REMARKS

By this Amendment, claims 1-37 are cancelled and new claims 38-73 are added. Support for the amendments comes generally from the specification and claims 1-37, as originally filed. Accordingly, no new matter is added. Currently, claims 38-73 are pending in this application.

I. *Claim Objections*

The Office objects to claims 18-26, 30, and 37 under 37 C.F.R. § 1.75(c) as being in improper form. (Office Action at paragraphs 1 and 2.) By this Amendment, claims 18-26, 30, and 37 are cancelled, rendering the objection moot. Therefore, Applicants request that the Office withdraw the objection under this rule.

Applicants respectfully traverse the objections as they might be applied to new claims 38-73, which have been added by this Amendment. New claims 38-73 have been written to ensure that they are in proper form. Applicants respectfully submit that the present claims satisfy the requirements of 37 C.F.R. § 1.75(c).

II. *Rejections Under 35 U.S.C. § 112, second paragraph*

The Office rejects claims 1-37 under 35 U.S.C. § 112, second paragraph, as indefinite. (Office Action at paragraphs 5-13.) By this Amendment, claims 1-37 are cancelled, rendering the rejections moot. Therefore, Applicants respectfully request that the Office withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Applicants respectfully traverse the rejections as they might be applied to new claims 38-73, which have been added by this Amendment. New claims 38-73 have been written to address

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

the issues raised in the Office Action. More specifically, none of new claims 38-73 recite the terms or phrases identified by the Office as indefinite. Accordingly, Applicants respectfully submit that the present claims satisfy the requirements of 35 U.S.C. § 112, second paragraph.

III. *Rejection Under 35 U.S.C. § 112, first paragraph*

The Office rejects claims 17-33 under 35 U.S.C. § 112, first paragraph, as not enabled for the full scope of the claims. (Office Action at paragraphs 3 and 4.) Specifically, the Office states that the claims are enabled for treatment, but not prevention, of conditions, diseases, and disorders resulting from oxidative stress. By this Amendment, claims 17-33 are cancelled, rendering the rejection moot. Therefore, Applicants request that the Office withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Applicants respectfully traverse the rejection as it might be applied to new claims 38-73, which have been added by this Amendment. New claims 57-73, the only claims that are directed to methods, are limited to methods of treating. Accordingly, Applicants respectfully submit that the present claims satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph.

IV. *Rejection Under 35 U.S.C. § 101*

The Office rejects claims 34-37 under 35 U.S.C. § 101 for claiming non-statutory subject matter (*i.e.,* for being "use" claims). (Office Action at paragraph 14.) By this Amendment, claims 34-37 are cancelled, rendering the rejection moot. Therefore, Applicants respectfully request that the Office withdraw the rejection under 35 U.S.C. § 101.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

Applicants respectfully traverse the rejection as it might be applied to new claims 38-73, which have been added by this Amendment. New claims 38-73 have been written to ensure that they are all directed to statutory subject matter. Accordingly, Applicants submit that the present claims satisfy the requirements of 35 U.S.C. § 101.

V. *Rejections Under 35 U.S.C. § 102*

A. Valducci (EP 0 820 703)

The Office rejects claims 1-16 under 35 U.S.C. § 102(b) as anticipated by Valducci (EP 0 820 703; "EP '703"). (Office Action at paragraph 16.) Specifically, the Office asserts that the compositions of EP '703 are considered to be identical to those of the claims of the present application, absent demonstration otherwise. By this Amendment, claims 1-16 are cancelled, rendering the rejection moot. Therefore, Applicants respectfully request that the Office withdraw the rejection. Applicants respectfully traverse the rejection as it might be applied to new claims 38-73.

While EP '703 discloses an oral prolonged release vitamin C / rapid-release vitamin E formulation, the only example of EP '703 directed to such a composition is Example 9. Example 9 of EP '703 teaches a unit dosage composition comprising tablets from Examples 5, 6, and 7. The unit dosage comprises 150 g of vitamin C and 30 mg of vitamin E. Thus, a single dose would deliver 150 g of vitamin C to the individual. EP '703 does not disclose or suggest any other amounts of the combination of both vitamins C and E.

wrong. Ex 10, 100

In contrast to EP '703, the presently claimed delivery system and methods deliver 60 mg to 2 g of vitamin C daily. Thus, the present invention recites daily delivery of amounts of

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

vitamin C that are outside the teaching of EP '703. Accordingly, Applicants respectfully submit that EP '703 does not anticipate the presently claimed invention.

B. DeFelice (U.S. Patent No. 5,560,928)

The Office rejects claims 1-11 and 13-16 under 35 U.S.C. § 102(b) as anticipated by DeFelice (U.S. Patent No. 5,560,928; "the '928 patent"). (Office Action at paragraph 17.) Specifically, the Office asserts that the compositions of the '928 patent are considered to be identical to those of the claims of the present application, absent demonstration otherwise. By this Amendment, claims 1-11 and 13-16 are cancelled, rendering the rejection moot. Therefore, Applicants respectfully request that the Office withdraw the rejection. Applicants respectfully traverse the rejection as it might be applied to new claims 38-73.

The '928 patent is directed to a once daily (24-hour) effervescent composition for dietary or nutritional supplementation. (See, for example, the '928 patent Abstract.) The composition provides active ingredients, such as vitamin C and vitamin E, in both free form (rapid or plain release) and micro-encapsulated form (sustained or slow release). The vitamins are provided in both forms to provide a continuous supply of them for an extended (24 hour) period. (See, for example, the '928 patent at column 4, lines 9-13.) That is, the mode of operation of the '928 patent is to provide a short-term delivery of nutritional and/or dietary supplements (*e.g.*, vitamins C and E) via rapid release, and a long-term delivery via sustained release. In view of the purpose of the compositions of the '928 patent, it does not disclose or suggest a composition that does not include each active ingredient in both rapid release and sustained release forms.

In contrast, the present claims are directed to achieving an optimal ratio of vitamins C and E in the blood plasma. The claims achieve this by providing vitamin C in a slow release form

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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only, and vitamin E in a plain release form only. Because the '928 patent does not disclose or suggest a combination of vitamin C in a slow release form only, and vitamin E in a plain release form only, the '928 patent does not anticipate the presently claimed invention.

VI. *Rejections Under 35 U.S.C. § 103*

A. Valducci (EP 0 820 703)

The Office rejects claims 1-16 under 35 U.S.C. § 103(a) as obvious over EP '703. (Office Action at paragraph 19.) By this Amendment, claims 1-16 are cancelled, rendering the rejection moot as it applies to these claims. Therefore, Applicants respectfully request that the Office withdraw the rejection. Applicants respectfully traverse the rejection as it might be applied to new claims 38-73.

As discussed above in section V.A., EP '703 does not disclose or suggest a composition comprising both vitamin C and vitamin E in amounts other than the amounts disclosed in Example 9, which discloses the use of 150 g of vitamin C. Although EP '703 does not suggest it, the Office asserts that it would be obvious to increase the amount of vitamins to address dietary deficiencies. As the Office apparently recognizes, however, there is no suggestion, or any type of motivation whatsoever, to decrease the amount of vitamin C delivered, much less a suggestion or motivation to decrease it to a level that is 75 times less than taught (as would be required for EP '703 to anticipate the vitamin E element of the present claims).

Furthermore, EP '703 is completely silent with respect to achieving the ratios of vitamin C to vitamin E in blood plasma that are recited in the present claims. That is, it neither discloses nor suggests that vitamin C and vitamin E should be supplied at a ratio, or to achieve a ratio,

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

according to any of present claims 38, 40, 41, 51, 57, 60, 66, 67, and 69. Indeed, EP '703 does not disclose or suggest that a particular ratio is preferable over any other ratio.

For at least these reasons, Applicants respectfully submit that EP '703 does not render the presently claimed invention obvious.

B. DeFelice (U.S. Patent No. 5,560,928)

The Office rejects claims 1-11 and 13-16 under 35 U.S.C. § 103(a) as obvious over the '928 patent. (Office Action at paragraph 20.) By this Amendment, claims 1-11 and 13-16 are cancelled, rendering the rejection moot as it applies to these claims. Therefore, Applicants respectfully request that the Office withdraw the rejection. Applicants respectfully traverse the rejection as it might be applied to new claims 38-73.

As discussed above in section V.B., although the '928 patent discloses a composition comprising both vitamin C and vitamin E, both vitamins must be present in both rapid release and sustained release forms in order to achieve its purpose of providing both short-term and long-term release of each vitamin. Because the '928 patent is limited to compositions comprising both rapid release and sustained release forms of each component, it does not and cannot suggest a composition, system, or method that comprises vitamin C in a sustained-release form only, and vitamin E in a plain release form only, as required by the present claims. Therefore, the '928 patent does not render obvious the presently claimed invention.

C. Valducci (EP 0 820 703) in view of Sato *et al.* or Niki

The Office rejects claims 17-37 under 35 U.S.C. § 103(a) as obvious over the '928 patent in view of Sato *et al.* or Niki. (Office Action at paragraph 22.) By this Amendment, claims 17-37 are cancelled, rendering the rejection moot as it applies to these claims. Therefore, Applicants

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

respectfully request that the Office withdraw the rejection. Applicants respectfully traverse the rejection as it might be applied to new claims 38-73.

As discussed above in sections V.A. and VI.A., EP '703 does not disclose or suggest a composition comprising both vitamin C and vitamin E in any amounts other than the amounts disclosed in Example 9, which discloses the use of 150 g of vitamin C. As recognized by the Office, EP '703 also does not disclose or suggest a composition for treatment of oxidative stress disorders. Furthermore, as apparently recognized by the Office, EP '703 does not suggest lowering the amount of vitamins provided by its compositions. Thus, in order for the combination of EP '703, Sato *et al.*, and/or Niki to render any of claims 38-73 obvious, either Sato *et al.* and/or Kiki must disclose or suggest modifying EP '703 by reducing the amount of vitamin C in the composition of EP '703 at least 75-fold, and using the modified composition to treat oxidative stress disorders.

Applicants respectfully submit that neither Sato *et al.* nor Niki discloses or suggests such a modification. Furthermore, neither discloses or suggests using such a composition to treat oxidative stress disorders. Accordingly, the combination of EP '703 and Sato *et al.*, and the combination of EP '703 and Kiki, fail to render the presently claimed invention obvious.

D. DeFelice (U.S. Patent No. 5,560,928) in view of Sato *et al.* or Niki

The Office rejects claims 17-37 under 35 U.S.C. § 103(a) as obvious over the '928 patent. (Office Action at paragraph 22.) By this Amendment, claims 17-37 are cancelled, rendering the rejection moot as it applies to these claims. Therefore, Applicants respectfully request that the Office withdraw the rejection. Applicants respectfully traverse the rejection as it might be applied to new claims 38-73.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

As discussed above in section V.B. and VI.B., the '928 patent discloses a composition comprising vitamins C and E. However, compositions that comprise these two vitamins must comprise them in both rapid release and sustained release forms. The vitamins are provided in both forms to provide a continuous supply of them for an extended (24 hour) period. (See, for example, the '928 patent at column 4, lines 9-13.) That is, as discussed above, the mode of operation of the '928 patent is to provide a short-term delivery of nutritional and/or dietary supplements (*e.g.*, vitamins C and E) via rapid release, and a long-term delivery via sustained release.

In contrast to EP '703, the presently claimed invention provides vitamin C in a sustained release form only, and vitamin E in a plain release form only. According to the present invention, these two vitamins can be delivered to an individual in defined ratios to treat oxidative stress disorders and associated diseases and conditions.

In order to render the presently claimed invention obvious, as proposed by the Office, among other things, one would need to modify the composition of the '928 patent such that it no longer included both a sustained release form and a plain release form of vitamins C and E. However, to do so would change the principle of operation of the '928 patent because it would no longer provide both vitamins in both a short-term and long-term delivery forms. If a proposed modification of a primary reference by a secondary reference would change the principle of operation of the primary reference, the teachings of the references are not sufficient to render the claims obvious. (MPEP § 2143.01, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).)

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

Therefore, because modifying the '928 patent as proposed by the Office would change the principle of operation of that reference, such a modification is improper and cannot be made. Accordingly, regardless of the teachings of Sato *et al.* or Niki, the presently claimed invention is not rendered obvious by the combination of the '928 patent with either Sato *et al.* or Niki.

VII. *Conclusion*

For at least the reasons set forth above, Applicants submit that this application is in condition for allowance. Therefore, Applicants request that the Office withdraw the outstanding objections and rejections, and permit this application to issue as a U.S. patent in due course. If the Examiner believes anything further is necessary in order to place this application in even better condition for allowance, he is invited to contact Applicants' undersigned representative at the telephone number or e-mail address below.

Please grant any extensions of time required to enter this Amendment, and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: 

Matthew T. Latimer
Reg. No. 44,024
(202) 408-4495
matthew.latimer@finnegan.com

Date: December 12, 2001

LAW OFFICES
FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000